IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ANACOR PHARMACEUTICALS, INC. and PF PRISM IMB B.V.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
ALKEM LABORATORIES LTD.,	)	
Defendant.	)	

COMPLAINT

Plaintiffs Anacor Pharmaceuticals, Inc. ("Anacor") and PF PRISM IMB B.V. (collectively, "Plaintiffs"), by their undersigned attorneys, for their Complaint for patent infringement against Defendant Alkem Laboratories Ltd. ("Alkem" or "Defendant"), allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, and the Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.*, arising from Alkem's submission of Abbreviated New Drug Application ("ANDA") No. 216301 to the United States Food and Drug Administration ("FDA"), seeking approval to market a generic version of Anacor's EUCRISA® (crisaborole) ointment, 2% prior to the expiration of U.S. Patent No. 8,039,451 ("the '451 patent"), U.S. Patent No. 8,168,614 ("the '614 patent"), U.S. Patent No. 8,501,712 ("the '712 patent"), and U.S. Patent No. 9,682,092 ("the '092 patent"). The '451 patent, the '614 patent, the '712 patent, and the '092 patent are referred to collectively in this Complaint as "the patents-in-suit."

THE PARTIES

2. Plaintiff Anacor is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 235 East 42nd Street, New York, NY 10017.

3. Plaintiff PF PRISM IMB B.V. is a private limited liability company (*besloten venootschap*) organized under the laws of the Netherlands, having its registered seat in Rotterdam, the Netherlands, and having its business address at Rivium Westlaan 142, 2909 LD, Capelle aan den IJessel, the Netherlands.

4. Upon information and belief, Defendant Alkem is a company organized and existing under the laws of India, having a principal place of business at Devashish Building, Alkem House, Senapati Bapat Road, Lower Parel, Mumbai, Maharashtra 400013, India.

5. Upon information and belief, Alkem is a generic pharmaceutical company that develops, manufactures, markets and distributes generic pharmaceutical products for sale in the State of Delaware and throughout the United States.

THE PATENTS-IN-SUIT

6. On October 18, 2011, the United States Patent and Trademark Office ("USPTO) duly and legally issued the '451 patent, entitled "Boron-Containing Small Molecules." A copy of the '451 patent is attached to this Complaint as Exhibit A.

7. Anacor is the owner and assignee of the '451 patent.

8. PF PRISM IMB B.V. is the exclusive licensee of the '451 patent.

9. On May 1, 2012, the USPTO duly and legally issued the '614 patent, entitled "Boron-Containing Small Molecules as Anti-Inflammatory Agents." A copy of the '614 patent is attached to this Complaint as Exhibit B.

10. Anacor is the owner and assignee of the '614 patent.

11. PF PRISM IMB B.V. is the exclusive licensee of the '614 patent.

12. On August 6, 2013, the USPTO duly and legally issued the '712 patent, entitled "Boron-Containing Small Molecules as Anti-Inflammatory Agents." A copy of the '712 patent is attached to this Complaint as Exhibit C.

13. Anacor is the owner and assignee of the '712 patent.

14. PF PRISM IMB B.V. is the exclusive licensee of the '712 patent.

15. On June 20, 2017, the USPTO duly and legally issued the '092 patent, entitled "Boron-Containing Small Molecules as Anti-Inflammatory Agents." A copy of the '092 patent is attached to this Complaint as Exhibit D.

16. Anacor is the owner and assignee of the '092 patent.

17. PF PRISM IMB B.V. is the exclusive licensee of the '092 patent.

EUCRISA®

18. Anacor holds approved New Drug Application No. 207695 for the use of crisaborole ointment, 2% (trade name EUCRISA®) for topical treatment of mild to moderate atopic dermatitis in adult and pediatric patients 3 months of age and older.

19. Pursuant to 21 U.S.C. § 355(c)(2), and attendant FDA regulations, the patents-in-suit are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to EUCRISA®.

ALKEM'S ANDA

20. Upon information and belief, Alkem prepared and submitted ANDA No. 216301 ("Alkem's ANDA") to the FDA in accordance with 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, or sale of crisaborole ointment, 2% ("Alkem's ANDA Product") before the expiration of the patents-in-suit.

21. Upon information and belief, Alkem's ANDA Product is a generic copy of EUCRISA®.

22. Upon information and belief, Alkem's ANDA refers to and relies upon Anacor's New Drug Application No. 207695 and purports to contain data on the bioequivalence of Alkem's ANDA Product to EUCRISA®.

23. By letter to Anacor, dated August 19 2021 ("Alkem's Paragraph IV Notice Letter"), Alkem stated that Alkem's ANDA contained certifications, pursuant to 21 U.S.C.

§ 355(j)(2)(A)(vii)(IV), that the patents-in-suit are not valid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of Alkem's ANDA Product (the "Paragraph IV Certification"). Alkem's Paragraph IV Notice Letter included a detailed statement, in which Alkem purported to allege the factual and legal bases for its Paragraph IV Certification.

24. Upon information and belief, if the FDA approves Alkem's ANDA, Defendant will manufacture, distribute, import, offer for sale and/or sell Alkem's ANDA Product throughout the United States, including within the State of Delaware.

25. This action is being filed within 45 days of Anacor's receipt of Alkem's Paragraph IV Notice Letter.

JURISDICTION AND VENUE

26. This case arises under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, and this Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

27. This Court has personal jurisdiction over Alkem because of its regular transaction and/or solicitation of business in this State. Upon information and belief, Alkem is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Alkem directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. By continuously placing its products into the stream of commerce for distribution and consumption in the State of Delaware, and throughout the United States, Alkem has engaged in the regular conduct of business within this judicial district.

28. Upon information and belief, Alkem submitted Alkem's ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or

importation of Alkem's ANDA Product in the United States, including in the State of Delaware.

29. Upon information and belief, upon approval of Alkem's ANDA, Alkem will market, distribute, offer for sale, and/or sell Alkem's ANDA Product in the United States, including in the State of Delaware.

30. This Court has personal jurisdiction over Alkem because of its regular transaction and/or solicitation of business in this State. Upon information and belief, Alkem is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Alkem directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. By continuously placing its products into the stream of commerce for distribution and consumption in the State of Delaware, and throughout the United States, Alkem has engaged in the regular conduct of business within this judicial district.

31. Upon information and belief, Defendants have previously been sued in this judicial district without challenging personal jurisdiction and have availed themselves of the jurisdiction of this Court by previously asserting counterclaims in this district. *See, e.g.*, *Otsuka Pharm. Co., Ltd. et al v. Alkem Lab'ys Ltd.,* C.A. No. 20-01286-LPS, *Azurity Pharms., Inc. v. Alkem Lab'ys Ltd.,* C.A. No. 20-1094-MSG, *BIAL-PORTELA & CA. S.A. et al v. Alkem Lab'ys Ltd. al,* C.A. No. 20-786-CFC.

32. Venue is proper in this Court for Alkem under 28 U.S.C. § 1391(c)(3) because, upon information and belief, Alkem is not a resident of the United States and may thus be sued in any judicial district.

COUNT I
(Infringement of the '451 Patent)

33. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

34. Defendant has infringed one or more claims of the '451 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting to the FDA and maintaining Alkem's ANDA, by which Defendant seeks approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of Alkem's ANDA Product prior to the expiration of the '451 patent.

35. Defendants' commercial manufacture, sale, offer for sale, or use of Alkem's ANDA Product within the United States, or importation of Alkem's ANDA Product into the United States, during the term of the '451 patent would infringe one or more claims of the '451 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

36. Defendant's commercial manufacture, sale, offer for sale, or use of Alkem's ANDA Product within the United States, or importation of Alkem's ANDA Product into the United States, during the term of the '451 patent would induce and/or contribute to the infringement of one or more claims of the '451 patent under 35 U.S.C. §§ 271(b) and/or (c).

37. Alkem's Paragraph IV Notice Letter does not dispute infringement of claims 1-4 of the '451 patent.

38. Claim 1 of the '451 patent recites "A compound which is 5-(4-cyanophenoxy)-1,3-dihydro-1-hydroxy-[2,l]-benzoxaborole," also known as crisaborole, which is the active ingredient in EUCRISA®.

39. Crisaborole is the active ingredient in Alkem's ANDA Product.

40. Upon information and belief, Defendant has acted with full knowledge of the '451 patent and without a reasonable basis for believing that it would not be liable for infringement of the '451 patent. Notwithstanding this knowledge, Defendant has continued to assert its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Alkem's ANDA Product with its proposed labeling immediately and imminently upon approval of Alkem's ANDA. Upon information and belief, through such activities, Defendant specifically intends infringement of the '451 patent.

41. Upon information and belief, if the FDA approves Alkem's ANDA, Defendant plans and intends to, and will, infringe, actively induce infringement of, and/or contribute to the infringement of the '451 patent, and will do so immediately and imminently upon approval.

42. Upon information and belief, Defendant knows that Alkem's ANDA Product is especially made or adapted for use in infringing the '451 patent, and that Alkem's ANDA Product is not suitable for any substantial non-infringing use. Upon information and belief, Defendant plans and intends to, and will, contribute to infringement of the '451 patent immediately and imminently upon approval of Alkem's ANDA.

43. Plaintiffs will be harmed substantially and irreparably if Defendant is not enjoined from infringing the '451 patent.

44. Plaintiffs have no adequate remedy at law.

45. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT II
(Declaratory Judgment of Infringement of the '451 Patent)

46. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

47. There is a substantial and immediate controversy between Plaintiffs and Alkem concerning the '451 patent. Plaintiffs are entitled to a declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that Alkem will infringe, actively induce infringement of, and/or contribute to the infringement of the '451 patent upon approval of Alkem's ANDA.

48. Defendants' commercial manufacture, sale, offer for sale, or use of Alkem's ANDA Product within the United States, or importation of Alkem's ANDA Product into the United States, during the term of the '451 patent would infringe one or more claims of the '451 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

49. Defendant's commercial manufacture, sale, offer for sale, or use of Alkem's ANDA Product within the United States, or importation of Alkem's ANDA Product into the

United States, during the term of the '451 patent would induce and/or contribute to the infringement of one or more claims of the '451 patent under 35 U.S.C. §§ 271(b) and/or (c).

50. Alkem's Paragraph IV Notice Letter does not dispute infringement of claims 1-4 of the '451 patent.

51. Claim 1 of the '451 patent recites "A compound which is 5-(4-cyanophenoxy)-1,3-dihydro-1-hydroxy-[2,l]-benzoxaborole," also known as crisaborole, which is the active ingredient in EUCRISA®.

52. Crisaborole is the active ingredient in Alkem's ANDA Product.

53. Upon information and belief, Defendant has acted with full knowledge of the '451 patent and without a reasonable basis for believing that it would not be liable for infringement of the '451 patent. Notwithstanding this knowledge, Defendant has continued to assert its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Alkem's ANDA Product with its proposed labeling immediately and imminently upon approval of Alkem's ANDA. Upon information and belief, through such activities, Defendant specifically intends infringement of the '451 patent.

54. Upon information and belief, if the FDA approves Alkem's ANDA, Defendant plans and intends to, and will, infringe, actively induce infringement of, and/or contribute to the infringement of the '451 patent, and will do so immediately and imminently upon approval.

55. Upon information and belief, Defendant knows that Alkem's ANDA Product is especially made or adapted for use in infringing the '451 patent, and that Alkem's ANDA Product is not suitable for any substantial non-infringing use. Upon information and belief, Defendant plans and intends to, and will, contribute to infringement of the '451 patent immediately and imminently upon approval of Alkem's ANDA.

56. Plaintiffs will be harmed substantially and irreparably if Defendant is not enjoined from infringing the '451 patent.

57. Plaintiffs have no adequate remedy at law.

58. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

59. The Court should declare that the commercial manufacture, use, sale, offer for sale and/or importation of Alkem's ANDA Product with its proposed labeling will infringe the '451 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

COUNT III
(Infringement of the '614 Patent)

60. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

61. Defendant has infringed one or more claims of the '614 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting to the FDA and maintaining Alkem's ANDA, by which Defendant seeks approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of Alkem's ANDA Product prior to the expiration of the '614 patent.

62. Defendants' commercial manufacture, sale, offer for sale, or use of Alkem's ANDA Product within the United States, or importation of Alkem's ANDA Product into the United States, during the term of the '614 patent would infringe one or more claims of the '614 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

63. Defendant's commercial manufacture, sale, offer for sale, or use of Alkem's ANDA Product within the United States, or importation of Alkem's ANDA Product into the United States, during the term of the '614 patent would induce and/or contribute to the infringement of one or more claims of the '614 patent under 35 U.S.C. §§ 271(b) and/or (c).

64. Alkem's Paragraph IV Notice Letter does not dispute infringement of claims 1-2, 4-8, 11-25, 29, and 31 of the '614 patent.

65. Claim 1 of the '614 patent covers a method of treating an inflammatory-related disease in a human or mammal, comprising administering a therapeutically effective amount of a crisaborole, which is the active ingredient in EUCRISA®.

66. EUCRISA® is approved for the topical treatment of mild to moderate atopic dermatitis in adult and pediatric patients 3 months of age or older.

67. Upon information and belief, the proposed labeling for Alkem's ANDA Product directs the use of Alkem's ANDA Product for treating mild to moderate atopic dermatitis, which is an inflammatory-related disease in a human or mammal, comprising administering a therapeutically effective amount of a crisaborole.

68. Upon information and belief, Defendant has acted with full knowledge of the '614 patent and without a reasonable basis for believing that it would not be liable for infringement of the '614 patent. Notwithstanding this knowledge, Defendant has continued to assert its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Alkem's ANDA Product with its proposed labeling immediately and imminently upon approval of Alkem's ANDA. Upon information and belief, through such activities, Defendant specifically intends infringement of the '614 patent.

69. Upon information and belief, if the FDA approves Alkem's ANDA, Defendant plans and intends to, and will, infringe, actively induce infringement of, and/or contribute to the infringement of the '614 patent, and will do so immediately and imminently upon approval.

70. Upon information and belief, Defendant know that Alkem's ANDA Product is especially made or adapted for use in infringing the '614 patent, and that Alkem's ANDA Product is not suitable for any substantial non-infringing use. Upon information and belief, Defendant plans and intends to, and will, contribute to infringement of the '614 patent immediately and imminently upon approval of Alkem's ANDA.

71. Plaintiffs will be harmed substantially and irreparably if Defendant is not enjoined from infringing the '614 patent.

72. Plaintiffs have no adequate remedy at law.

73. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT IV
(Declaratory Judgment of Infringement of the '614 Patent)

74. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

75. There is a substantial and immediate controversy between Plaintiffs and Alkem concerning the '614 patent. Plaintiffs are entitled to a declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that Alkem will infringe, actively induce infringement of, and/or contribute to the infringement of the '614 patent upon approval of Alkem's ANDA.

76. Defendants' commercial manufacture, sale, offer for sale, or use of Alkem's ANDA Product within the United States, or importation of Alkem's ANDA Product into the United States, during the term of the '614 patent would infringe one or more claims of the '614 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

77. Defendant's commercial manufacture, sale, offer for sale, or use of Alkem's ANDA Product within the United States, or importation of Alkem's ANDA Product into the United States, during the term of the '614 patent would induce and/or contribute to the infringement of one or more claims of the '614 patent under 35 U.S.C. §§ 271(b) and/or (c).

78. Alkem's Paragraph IV Notice Letter does not dispute infringement of claims 1-2, 4-8, 11-25, 29, and 31 of the '614 patent.

79. Claim 1 of the '614 patent covers a method of treating an inflammatory-related disease in a human or mammal, comprising administering a therapeutically effective amount of a crisaborole, which is the active ingredient in EUCRISA®.

80. EUCRISA® is approved for the topical treatment of mild to moderate atopic dermatitis in adult and pediatric patients 3 months of age or older.

81. Upon information and belief, the proposed labeling for Alkem's ANDA Product directs the use of Alkem's ANDA Product for treating mild to moderate atopic dermatitis,

which is an inflammatory-related disease in a human or mammal, comprising administering a therapeutically effective amount of a crisaborole.

82. Upon information and belief, Defendant has acted with full knowledge of the '614 patent and without a reasonable basis for believing that it would not be liable for infringement of the '614 patent. Notwithstanding this knowledge, Defendant has continued to assert its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Alkem's ANDA Product with its proposed labeling immediately and imminently upon approval of Alkem's ANDA. Upon information and belief, through such activities, Defendant specifically intends infringement of the '614 patent.

83. Upon information and belief, if the FDA approves Alkem's ANDA, Defendant plans and intends to, and will, infringe, actively induce infringement of, and/or contribute to the infringement of the '614 patent, and will do so immediately and imminently upon approval.

84. Upon information and belief, Defendant know that Alkem's ANDA Product is especially made or adapted for use in infringing the '614 patent, and that Alkem's ANDA Product is not suitable for any substantial non-infringing use. Upon information and belief, Defendant plans and intends to, and will, contribute to infringement of the '614 patent immediately and imminently upon approval of Alkem's ANDA.

85. Plaintiffs will be harmed substantially and irreparably if Defendant is not enjoined from infringing the '614 patent.

86. Plaintiffs have no adequate remedy at law.

87. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

88. The Court should declare that the commercial manufacture, use, sale, offer for sale and/or importation of Alkem's ANDA Product with its proposed labeling will infringe the '614 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

COUNT V
(Infringement of the '712 Patent)

89. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

90. Defendant has infringed one or more claims of the '712 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting to the FDA and maintaining Alkem's ANDA, by which Defendant seeks approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of Alkem's ANDA Product prior to the expiration of the '712 patent.

91. Defendants' commercial manufacture, sale, offer for sale, or use of Alkem's ANDA Product within the United States, or importation of Alkem's ANDA Product into the United States, during the term of the '712 patent would infringe one or more claims of the '712 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

92. Defendant's commercial manufacture, sale, offer for sale, or use of Alkem's ANDA Product within the United States, or importation of Alkem's ANDA Product into the United States, during the term of the '712 patent would induce and/or contribute to the infringement of one or more claims of the '712 patent under 35 U.S.C. §§ 271(b) and/or (c).

93. Alkem's Paragraph IV Notice Letter does not dispute infringement of claims 1-4, 7, and 9 of the '712 patent.

94. Claim 1 of the '712 patent covers a method of treating an inflammatory-related disease in a human or mammal, comprising administering a therapeutically effective amount of a crisaborole, which is the active ingredient in EUCRISA®.

95. EUCRISA® is approved for the topical treatment of mild to moderate atopic dermatitis in adult and pediatric patients 3 months of age or older.

96. Upon information and belief, the proposed labeling for Alkem's ANDA Product directs the use of Alkem's ANDA Product for treating mild to moderate atopic dermatitis, which is an inflammatory-related disease in a human or mammal, comprising administering a therapeutically effective amount of a crisaborole.

97. Upon information and belief, Defendant have acted with full knowledge of the '712 patent and without a reasonable basis for believing that it would not be liable for infringement of the '712 patent. Notwithstanding this knowledge, Defendant has continued to assert its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Alkem's ANDA Product with its proposed labeling immediately and imminently upon approval of Alkem's ANDA. Upon information and belief, through such activities, Defendant specifically intend infringement of the '712 patent.

98. Upon information and belief, if the FDA approves Alkem's ANDA, Defendant plans and intends to, and will, infringe, actively induce infringement of, and/or contribute to the infringement of the '712 patent, and will do so immediately and imminently upon approval.

99. Upon information and belief, Defendant knows that Alkem's ANDA Product is especially made or adapted for use in infringing the '712 patent, and that Alkem's ANDA Product is not suitable for any substantial non-infringing use. Upon information and belief, Defendant plans and intends to, and will, contribute to infringement of the '712 patent immediately and imminently upon approval of Alkem's ANDA.

100. Plaintiffs will be harmed substantially and irreparably if Defendant is not enjoined from infringing the '712 patent.

101. Plaintiffs have no adequate remedy at law.

102. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT VI
(Declaratory Judgment of Infringement of the '712 Patent)

103. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

104. There is a substantial and immediate controversy between Plaintiffs and Alkem concerning the '712 patent. Plaintiffs are entitled to a declaratory judgment under 28 U.S.C.

§§ 2201 and 2202 that Alkem will infringe, actively induce infringement of, and/or contribute to the infringement of the '712 patent upon approval of Alkem's ANDA.

105. Defendants' commercial manufacture, sale, offer for sale, or use of Alkem's ANDA Product within the United States, or importation of Alkem's ANDA Product into the United States, during the term of the '712 patent would infringe one or more claims of the '712 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

106. Defendant's commercial manufacture, sale, offer for sale, or use of Alkem's ANDA Product within the United States, or importation of Alkem's ANDA Product into the United States, during the term of the '712 patent would induce and/or contribute to the infringement of one or more claims of the '712 patent under 35 U.S.C. §§ 271(b) and/or (c).

107. Alkem's Paragraph IV Notice Letter does not dispute infringement of claims 1-4, 7, and 9 of the '712 patent.

108. Claim 1 of the '712 patent covers a method of treating an inflammatory-related disease in a human or mammal, comprising administering a therapeutically effective amount of a crisaborole, which is the active ingredient in EUCRISA®.

109. EUCRISA® is approved for the topical treatment of mild to moderate atopic dermatitis in adult and pediatric patients 3 months of age or older.

110. Upon information and belief, the proposed labeling for Alkem's ANDA Product directs the use of Alkem's ANDA Product for treating mild to moderate atopic dermatitis, which is an inflammatory-related disease in a human or mammal, comprising administering a therapeutically effective amount of a crisaborole.

111. Upon information and belief, Defendant have acted with full knowledge of the '712 patent and without a reasonable basis for believing that it would not be liable for infringement of the '712 patent. Notwithstanding this knowledge, Defendant has continued to assert its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing,

distribution and/or importation of Alkem's ANDA Product with its proposed labeling immediately and imminently upon approval of Alkem's ANDA. Upon information and belief, through such activities, Defendant specifically intend infringement of the '712 patent.

112. Upon information and belief, if the FDA approves Alkem's ANDA, Defendant plans and intends to, and will, infringe, actively induce infringement of, and/or contribute to the infringement of the '712 patent, and will do so immediately and imminently upon approval.

113. Upon information and belief, Defendant knows that Alkem's ANDA Product is especially made or adapted for use in infringing the '712 patent, and that Alkem's ANDA Product is not suitable for any substantial non-infringing use. Upon information and belief, Defendant plans and intends to, and will, contribute to infringement of the '712 patent immediately and imminently upon approval of Alkem's ANDA.

114. Plaintiffs will be harmed substantially and irreparably if Defendant is not enjoined from infringing the '712 patent.

115. Plaintiffs have no adequate remedy at law.

116. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

117. The Court should declare that the commercial manufacture, use, sale, offer for sale and/or importation of Alkem's ANDA Product with its proposed labeling will infringe the '712 patent under at least 35 U.S.C. §§ 271(a), (b), and/or (c).

COUNT VII
(Infringement of the '092 Patent)

118. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

119. Defendant has infringed one or more claims of the '092 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting to the FDA and maintaining Alkem's ANDA, by which Defendant seeks approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of Alkem's ANDA Product prior to the expiration of the '092 patent.

120. Defendants' commercial manufacture, sale, offer for sale, or use of Alkem's ANDA Product within the United States, or importation of Alkem's ANDA Product into the United States, during the term of the '092 patent would infringe one or more claims of the '092 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

121. Defendant's commercial manufacture, sale, offer for sale, or use of Alkem's ANDA Product within the United States, or importation of Alkem's ANDA Product into the United States, during the term of the '092 patent would induce and/or contribute to the infringement of one or more claims of the '092 patent under 35 U.S.C. §§ 271(b) and/or (c).

122. Alkem's Paragraph IV Notice Letter does not dispute infringement of claims 1-6, 12, 14, 16-17, 19, and 21-26 of the '092 patent.

123. Claim 1 of the '092 patent covers a method of treating an inflammatory-related disease in a human or mammal, comprising administering a therapeutically effective amount of a crisaborole, which is the active ingredient in EUCRISA®.

124. EUCRISA® is approved for the topical treatment of mild to moderate atopic dermatitis in adult and pediatric patients 3 months of age or older.

125. Upon information and belief, the proposed labeling for Alkem's ANDA Product directs the use of Alkem's ANDA Product for treating mild to moderate atopic dermatitis, which is an inflammatory-related disease in a human or mammal, comprising administering a therapeutically effective amount of a crisaborole.

126. Upon information and belief, Defendant has acted with full knowledge of the '092 patent and without a reasonable basis for believing that it would not be liable for infringement of the '092 patent. Notwithstanding this knowledge, Defendant has continued to assert its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Alkem's ANDA Product with its proposed labeling

immediately and imminently upon approval of Alkem's ANDA. Upon information and belief, through such activities, Defendant specifically intends infringement of the '092 patent.

127. Upon information and belief, if the FDA approves Alkem's ANDA, Defendant plans and intends to, and will, infringe, actively induce infringement of, and/or contribute to the infringement of the '092 patent, and will do so immediately and imminently upon approval.

128. Upon information and belief, Defendant knows that Alkem's ANDA Product is especially made or adapted for use in infringing the '092 patent, and that Alkem's ANDA Product is not suitable for any substantial non-infringing use. Upon information and belief, Defendant plans and intends to, and will, contribute to infringement of the '092 patent immediately and imminently upon approval of Alkem's ANDA.

129. Plaintiffs will be harmed substantially and irreparably if Defendant is not enjoined from infringing the '092 patent.

130. Plaintiffs have no adequate remedy at law.

131. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT VIII
(Declaratory Judgment of Infringement of the '092 Patent)

132. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

133. There is a substantial and immediate controversy between Plaintiffs and Alkem concerning the '092 patent. Plaintiffs are entitled to a declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that Alkem will infringe, actively induce infringement of, and/or contribute to the infringement of the '092 patent upon approval of Alkem's ANDA.

134. Defendants' commercial manufacture, sale, offer for sale, or use of Alkem's ANDA Product within the United States, or importation of Alkem's ANDA Product into the United States, during the term of the '092 patent would infringe one or more claims of the '092 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

135. Defendant's commercial manufacture, sale, offer for sale, or use of Alkem's ANDA Product within the United States, or importation of Alkem's ANDA Product into the United States, during the term of the '092 patent would induce and/or contribute to the infringement of one or more claims of the '092 patent under 35 U.S.C. §§ 271(b) and/or (c).

136. Alkem's Paragraph IV Notice Letter does not dispute infringement of claims 1-6, 12, 14, 16-17, 19, and 21-26 of the '092 patent.

137. Claim 1 of the '092 patent covers a method of treating an inflammatory-related disease in a human or mammal, comprising administering a therapeutically effective amount of a crisaborole, which is the active ingredient in EUCRISA®.

138. EUCRISA® is approved for the topical treatment of mild to moderate atopic dermatitis in adult and pediatric patients 3 months of age or older.

139. Upon information and belief, the proposed labeling for Alkem's ANDA Product directs the use of Alkem's ANDA Product for treating mild to moderate atopic dermatitis, which is an inflammatory-related disease in a human or mammal, comprising administering a therapeutically effective amount of a crisaborole.

140. Upon information and belief, Defendant has acted with full knowledge of the '092 patent and without a reasonable basis for believing that it would not be liable for infringement of the '092 patent. Notwithstanding this knowledge, Defendant has continued to assert its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Alkem's ANDA Product with its proposed labeling immediately and imminently upon approval of Alkem's ANDA. Upon information and belief, through such activities, Defendant specifically intends infringement of the '092 patent.

141. Upon information and belief, if the FDA approves Alkem's ANDA, Defendant plans and intends to, and will, infringe, actively induce infringement of, and/or contribute to the infringement of the '092 patent, and will do so immediately and imminently upon approval.

142. Upon information and belief, Defendant knows that Alkem's ANDA Product is especially made or adapted for use in infringing the '092 patent, and that Alkem's ANDA Product is not suitable for any substantial non-infringing use. Upon information and belief, Defendant plans and intends to, and will, contribute to infringement of the '092 patent immediately and imminently upon approval of Alkem's ANDA.

143. Plaintiffs will be harmed substantially and irreparably if Defendant is not enjoined from infringing the '092 patent.

144. Plaintiffs have no adequate remedy at law.

145. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

146. The Court should declare that the commercial manufacture, use, sale, offer for sale and/or importation of Alkem's ANDA Product with its proposed labeling will infringe the '092 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for a judgment in its favor and against Defendant and respectfully requests the following relief:

A. A judgment that Defendant has infringed the patents-in-suit pursuant to 35 U.S.C. § 271(e)(2)(A) by submitting to the FDA and maintaining ANDA No. 216301;

B. An order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of approval of ANDA No. 216301 shall be a date not earlier than the expiration of the patents-in-suit, or any later expiration of exclusivity to which Anacor is or becomes entitled;

C. A judgment declaring that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Alkem's ANDA Product will directly infringe, induce and/or contribute to infringement of the patents-in-suit;

D. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Defendant, its officers, agents, servants, and employees, and those persons acting in privity or concert with them, from manufacturing, using, offering to sell, or selling Alkem's ANDA Product within the United States, or importing Alkem's ANDA Product into the United States, prior to the expiration of the patents-in-suit, or any later expiration of exclusivity to which Anacor is or becomes entitled;

E. If Defendant commercially manufactures, uses, offers to sell, or sells Alkem's ANDA Product within the United States, or imports Alkem's ANDA Product into the United States, prior to the expiration of the patents-in-suit, including any extensions, a judgment awarding damages to Plaintiffs resulting from such infringement, together with interest;

F. A judgment that this is an exceptional case pursuant to 35 U.S.C. § 285 and awarding Plaintiffs their attorneys' fees incurred in this action;

G. A judgment awarding Plaintiffs costs and expenses incurred in this action; and

H. Such further and other relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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